

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET N	O. CONFIRMATION NO.	
09/891,287 06/27/2001 Masahiro Kakehi 210098US0	1859	
22850 7590 07/09/2002		
	EXAMINER	
1733 JEFFERSON DAVIS HIGHWAT	SLOBODYANSKY, ELIZABETH	
ARLINGTON, VA 22202 ART UNIT	PAPER NUMBER	
1652	9	
DATE MAILED: 07/09/	I	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Applicati n No.	Applicant(s)
Office Action Summan	09/891,287	KAKEHI ET AL.
Office Action Summary	Examiner	Art Unit
	Elizabeth Slobodyansky	1652
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status		
1) Responsive to communication(s) filed on 29 C	<u> October 2001</u> .	
2a) This action is FINAL . 2b) ☐ Thi	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims		
4)⊠ Claim(s) <u>1-8</u> is/are pending in the application.		
4a) Of the above claim(s) <u>1-3 and 6-8</u> is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>4 and 5</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement. Application Papers		
9) The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) \square The proposed drawing correction filed on is: a) \square approved b) \square disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12)☐ The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a)⊠ All b)□ Some * c)□ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.8	5) Notice of Informal Pa	PTO-413) Paper No(s) stent Application (PTO-152)

Application/Control Number: 09/891,287 Page 2

Art Unit: 1652

DETAILED ACTION

The amendment filed October 29, 2001 amending the specification to replace the Sequence Listing has been entered.

Claims 1-8 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-3, drawn to a method for producing nucleoside 5'-phosphate ester, classified in class 435, subclass 85.
- Claims 4 and 5, drawn to an *Escherichia* bacterium, classified in class
 435, subclass 252.33.
- III. Claims 6-8, drawn to a method for searching for a 5'-nucleotidase gene, classified in class 435, subclass 34.

Inventions I and III are patentably distinct as drawn to materially different methods such as a method of making nucleoside 5'-phosphate ester and a method for identifying a specific microorganism, said methods using different protocols, chemicals and utilities.

Inventions I and II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, genes that do not function normally are not necessarily disrupted. *Escherichia* cell can be used as a host cell for the recombinant production of various proteins. Furthermore, nucleoside 5'-phosphate ester can be produced by a different method such as chemical synthesis.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Thomas Barnes on July 1, 2002 a provisional election was made with traverse to prosecute the invention of Group II, claims 4 and 5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-3 and 6-8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Art Unit: 1652

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites *Escherichia* "ushA gene" and "aphA gene". The specification defines *E. coli ushA* gene as GenBank accession X03895 and *E. coli aphA* gene as GenBank accession X86971(page 6, lines 18-20, and page 7, lines 16-22, respectively). The specification does not define sequences encompassed by the terms "ushA gene" or "aphA gene" of the genus *Escherichia* rendering the metes and bounds of the claim unascertainable.

Claim 5 refers to 5'-inosinic <u>acid</u> or 5'-guanylic <u>acid</u> as 5'-phosphate <u>ester</u> (emphasis added).

Application/Control Number: 09/891,287

Art Unit: 1652

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Laird et al.

Laird et al. (form PTO-1449 filed March 5, 2002, reference AW) teach an *E. coli* mutant strain, 54G2, having non-functional *ushA* and *aphA* genes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thaller et al. alone or in view of Cowman et al.

Thaller et al. (form PTO-1449 filed September 26, 2001, reference AW) teach the sequence of the *aphA* gene (page 193, Figure 1). They further characterize 5'-

Application/Control Number: 09/891,287 Page 6

Art Unit: 1652

nucleotidase activity of the *E. coli* AphA enzyme (page 195, Table 1). They teach that another 5'-nucleotidase in *E. coli* is UshA (page 197, 2nd column, last paragraph). They suggest producing strains carrying *aphA* mutations (page 198).

Cowman et al. (form PTO-1449 filed September 26, 2001, reference AV) teach the *ushA* gene from *E. coli* encoding a 5'-nucleotidase.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce *E. coli* mutants having non-functional, for example disrupted, *ushA* gene and *aphA* gene. The motivation to produce such mutants is provided by Thaller et al. who teach 5'-nucleotide dephosphorylating activity of *ushA* gene and *aphA* gene. Mutants with disrupted *ushA* gene and *aphA* gene would have a higher yield of 5'-nucleotides. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because the structures of both *ushA* gene and *aphA* gene were known at the time the invention was made and methods for disrupting known genes were widely used.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

Elizabeth Slobodyansky, PhD

Primary Examiner

July 1, 2002